

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name:	ACE Surgical Supply Co., Inc.
Submitter Address :	1034 Pearl St., Brockton, MA 02301
Contact Person:	J. Edward Carchidi, DDS
Phone Number:	(508) 588-3100
Fax Number:	(508) 523-3140
Date Prepared:	November, 2007
Device Trade Name:	ACE Surgical Secure-Mini™ Implant System
Device Common Name:	Endosseous Implant Screw
Classification Name:	Implant, Endosseous, Root form, product code DZE
Predicate device:	ACE Surgical Miniboneplate system, K951392
Reason for submission:	Intra-Lock International Mini Drive-Lock™ Implant System, K070601 Not previously marketed in the USA

Device Description and Materials:

The ACE Surgical Secure-Mini™ Implant System is a set of machined surgical grade titanium alloy screws, intended to provide immediate transitional splinting stability or intra-bony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients. The implants are supplied sterile in 2.3 mm diameter, and in lengths of 10, 11.5, 13, and 15 mm, in standard trays and include placement instruments. The screw raw material is Ti-6-AL-4V ELI per ASTM F136 standard. The candidate devices are identical in materials and characteristics to that cleared under K951392. These screws are supplied sterile in standard Tyvek™ trays. The ACE Surgical Secure-Mini™ Implant System is a comprehensive system retaining prosthetic components, auxiliary components, and surgical tools as does the predicate ACE Surgical Miniboneplate system.

Intended Use:

The ACE Surgical Secure-Mini™ Implant System is intended to provide immediate transitional splinting stability or intra-bony long-term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients.

Substantial Equivalence/ Device - Technological Characteristics and Comparison to Predicate Device(s):

The ACE Surgical Secure-Mini™ Implant System is substantially equivalent to the Intra-Lock International Mini Drive-Lock™ Implant System, K070601 and ACE Surgical Screw Miniboneplate System, K951392

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE Surgical Secure-Mini™ Implant System to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the ACE Surgical Prov+ Screw System and the specified predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. J. Edward Carchidi
President
ACE Surgical Supply Company, Limited
1034 Pearl Street
Brockton, Massachusetts 02301

MAR 13 2008

Re: K073343

Trade/Device Name: ACE Surgical Secure-Mini™ Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 6, 2008
Received: February 7, 2008

Dear Dr. Carchidi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

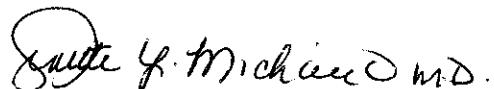
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K0703343

Device Name: ACE Surgical Secure-Mini™ Implant System

Indications For Use:

The ACE Surgical Secure-Mini™ Implant System is designed to provide immediate transitional splinting stability or intra-bony long term fixation of new or existing crown, bridge and denture installations in partially or fully edentulous patients.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sue Rivers
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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